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                      UNITED STATES DISTRICT COURT
                     FOR THE DISTRICT OF NEW JERSEY
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                                    CIVIL ACTION NUMBER:
    TEVA BRANDED PHARMACEUTICAL
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    PRODUCTS R&D, INC., and
                                    20 Civ. 10172 (JXN)
    NORTON (WATERFORD) LTD.,
 6
                                    FINAL PRETRIAL CONFERENCE
         Plaintiffs,
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          \boldsymbol{v}.
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    CIPLA., AUROBINDO PHARMA
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    LLC, AUROBINDO PHARMA USA,
    INC., and AUROLIFE PHARMA
10
    LLC,
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         Defendants.
12
         Martin Luther King Building & U.S. Courthouse
13
         50 Walnut Street
         Newark, New Jersey 07101
14
         Thursday, November 10, 2022
         Commencing at 10:32 a.m.
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    BEFORE:
                              THE HONORABLE JULIEN XAVIER NEALS
                              UNITED STATES DISTRICT JUDGE
17
    APPEARANCES:
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         For the Defendant Aurobindo
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              (PROCEEDINGS held in open court before The Honorable
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    JULIEN XAVIER NEALS, United States District Judge, at 10:32
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    a.m.)
             THE COURTROOM DEPUTY: All rise.
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             The Honorable Julien Xavier Neals presiding.
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             THE COURT: Good morning, Counsel.
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           Please be seated.
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             THE COURTROOM DEPUTY: We are on the record in
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    Teva Branded Pharmaceutical, Products R&D, Inc., et. al. v.
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    Cipla, LTD, et. al; case number 20 Civ. 10172.
11
             THE COURT: Counsel, your appearances, please.
12
             MR. WALSH: Good morning, your Honor.
13
           William Walsh, of Walsh Pizzi O'Reilly Falanga, on
14
    behalf of plaintiff Teva.
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           With me is my co-counsel from Williams & Connolly, and I
16
    will let them introduce themselves.
17
             MR. GREENBLUM: Good morning, your Honor.
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           Ben Greenblum, from Williams & Connolly for Teva; and
    with me are my colleagues, Ben Picozzi and Kat Kayali, also
19
20
    from Williams & Connolly.
21
             THE COURT: Good morning, Counsel.
22
             MR. KANG: Good morning, your Honor.
23
           Gene Kang, from Rivkin Radler LLP, for defendant Cipla
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    Limited. I am joined by co-counsel, William Adams, Bill
25
    Zimmerman, Brandon Smith, and Jonathan Bachand from Knobbe
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    Martens.
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             THE COURT: Good morning.
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             MR. CASIERI: Good morning.
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           Chris Casieri, McNeely, Hare & War, for Aurobindo.
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             THE COURT: Good morning.
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             MR. CASIERI: Good morning.
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             THE COURT: All right.
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           Counsel, we are here for the housekeeping, the long
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    awaited housekeeping in this case.
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           Just with the matter of housekeeping, I note that there
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    was a file pretrial that was provided today, a revised
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    pretrial.
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           I also note that we have the motion pending with regard
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    to Counts 5 and 11 as to Cipla's answer, defenses and
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    counterclaim and also with regard to the open matter as to the
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    Markman decision.
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           With regard to the final pretrial, someone either partly
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    summarize for the Court what was in today's final pretrial,
19
    what the modifications were to the last pretrial order?
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             MR. GREENBLUM: Good morning, your Honor.
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    Ben Greenblum, again from Williams & Connolly.
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           The pretrial order, I believe it was submitted -- the
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    revised one was submitted on Friday, and I think it was entered
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    by Magistrate Judge Hammer yesterday.
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           In substance, it -- I would describe it as making two
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changes, one is that it reflects where the parties are at --
and by parties I mean Teva and Cipla, not Aurobindo -- with
respect to this dispute on the '156 patent that your Honor will
be hearing more about this morning. And so we sort of tee'd
that up in the revised pretrial order to say if it's in, here's
what happens. If it's not in, here is what happens.
       The second issue is that we informed the defendants that
there were a few claims of patents that are remaining in the
case that we will not be proceeding on at trial, and so the
parties just agreed to remove the to and the fro, if you will,
about those claims from the pretrial order.
       Those are the only substantive changes I can recall.
I'm happy to be corrected if --
         MR. ADAMS: That's right, your Honor.
       William Adams, for the Cipla defendants.
       I think that's accurate.
       I mean, there are some housekeeping, when this hearing
occurred, that was updated, those types of things.
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I think substantively that is correct.

THE COURT: All right. Counsel, you just had mentioned with regard to the '156 patent, did you want to have a discussion about that now?

Was there some things that the parties wanted to point out with regard to that now?

MR. GREENBLUM: We were hoping to present brief

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    argument, if it was acceptable to the Court.
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           And my colleague, Mr. Picozzi, will be handling that for
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    Teva whenever the Court is prepared to hear it.
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             THE COURT: I would actually propose, unless the
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    parties have different thoughts on it, to have arguments on
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    '156 now, as a matter of fact.
 7
             MR. GREENBLUM: That's acceptable, certainly, to Teva,
 8
    your Honor.
 9
             MR. ADAMS:
                         That's fine, your Honor.
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             THE COURT: All right.
11
           So you can proceed on that.
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             MR. PICOZZI: Good morning, your Honor.
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             THE COURT: Good morning.
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             MR. PICOZZI: Ben Picozzi, for the plaintiff.
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             THE COURT: Good morning.
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             MR. PICOZZI: As we said in our briefs, we think that
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    this issue is straightforward.
18
           The relative facts are -- the relevant facts are not in
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    dispute here.
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           Everyone agrees that for the only potential basis that
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    this Court could possibly have for jurisdiction over the '156
22
    patent is the possibility that a judgment for Cipla on that
23
    patent could be used to trigger the forfeiture of the first
24
    applicant's exclusivity.
25
           Everyone also agrees that to do that Cipla needs to
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complete a complicated jigsaw puzzle of events. And everyone also agrees that Cipla can't do that based on the patents and claims that it has currently pending.

As we've laid out in our briefing, there are at least three patents that Cipla would need to get judgments in order for it to even have a hope of triggering forfeiture, that is the '156 patent, which is the patent at issue in Teva's motion, but also the '509 and '510 patents.

The parties agreed and this Court entered an order more than a year ago that dismissed their claims as to the '509 and '510 patents.

Those patents are out of this case and Cipla does not have any pending litigation anywhere in the world as to those patents.

And that is a fundamental problem for Cipla because courts from the Supreme Court on down have applied what is commonly referred to as the rule against piecemeal litigation. And that means that jurisdiction does not exist unless, based on pending litigation, a requested judgment would have some kind of effect that would completely resolve the parties' dispute, the case in controversy in question.

Now, Cipla's response to that is to say that this is a special Hatch-Waxman case and so a different result should be obtained here.

The problem for Cipla, though, is that there is no

special rule for Hatch-Waxman cases.

In fact, you know, we think it's ironic that they spent a lot of time trying to distinguish the nonHatch-Waxman cases because many of the cases that were relied in our opening brief, to give you a couple of examples, the *Dey* case, the *Janssen* case as well as the *Impax* case, which are cited on pages 7 through 10 of our opening brief, as well as the *Caraco* case, which is discussed in the opposition and reply briefs, are all Hatch-Waxman cases.

And in each of those cases, the Courts applied a rule that is consistent with the rule against piecemeal litigation.

And, you know, unless the Court needs any clearer indication that the same rules apply in Hatch-Waxman cases as in the ordinary course, it need look no further than the Dey Pharma case, which is quoted, in relevant part, both in our opening brief as well as page 12 of Cipla's opposition.

And in that case, the Court said upholding jurisdiction simply eliminating one barrier, by which it meant one patent, is sufficient for declaratory judgment, quote, so long as litigation is also pending that would eliminate the other barriers.

In other words, in that case, Hatch-Waxman case, the Court directly applied the rule against piecemeal litigation and found that jurisdiction existed in that basis because the declaratory judgment plaintiff there did, in fact, have pending

litigation as to all of the relevant patents.

That's, of course, not the case here where Cipla would need further additional nonfiled litigation on the '509 and '510 patents for it to meet the jurisdictional limit.

You know, as further evidenced that the ordinary rules apply in Hatch-Waxman cases, the federal circuit then turned around and reaffirmed that principle in the *AbbVie* case, which was not the Hatch-Waxman case. It was an ordinary patent case that also involved the contract license dispute.

In that case, the federal circuit held that because a judgment on just the patent claim without a further litigation over the underlying contractual dispute would have no effect on the parties ultimate dispute, that jurisdiction did not exist. And as support for that rule, it quoted that very same passage from Dey and said that because the parties' case or controversy could not be resolved based on pending litigation, that the Court didn't have jurisdiction and, therefore, dismissal was required.

One last brief point, your Honor, unless your Honor has further questions, throughout their opposition, Cipla argues that this Court should hear arguments, should maintain proceedings because it's too late; because the interest of efficiency and fairness would be served for this Court to hear argument.

Frankly, your Honor, you know, our client and theirs

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           And so I don't think we have a real dispute there.
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           The dispute is: Does there have to be pending
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    litigation on the '509 and '510 patents?
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           And I'm going to give you some context on that, and then
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    go through the law on it.
 6
           And the context is the '509 and '510 patents were
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    originally in this case at an early stage.
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           They were dismissed in May of '21 when there were still
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    numerous patents in play, and so it was an early stage.
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           The '156 patent has been in the case in its entirety.
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    They filed the covenant at the pretrial conference, said we
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    would be dismissing it, and then there were two weeks
13
    afterwards.
14
           So there was no reason to file a DJ on the '509 and '510
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              The timing of that DJ didn't impact anything.
16
    Certainly, not with respect to the '156 patent because it was
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    in the case.
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           And so where does Cipla have to go to clear the path to
19
    get to the market?
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           Counsel described it as a complicated jigsaw puzzle.
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           It is really very straightforward.
22
           They have to win on the patents that we are going to go
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    to trial on starting Monday and that includes the '156 -- or
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    doesn't depending on your ruling.
25
           We have to obtain a judgment on the '156 patent, a final
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    judgment of noninfringement or invalidity either in this case
    or a follow-on case.
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           And then we have to get a judgment on the '509 and '510
    patents, which Teva has already conceded they are not going to
    assert against us, and they've already told us we don't
 6
    infringe the '156 patent.
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           So those last two pieces should be straightforward and
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    easy.
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           The question is whether the '156 patent is at issue in
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    this case.
11
           Now, there's no dispute that there isn't current pending
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    litigation on the '509 and '510 patents, but Cipla doesn't
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    believe that that's required under the all circumstances test
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    for subject matter jurisdiction under the federal circuit
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    precedent.
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           Now, counsel referred to three cases, Dey, Janssen and
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    Impax, and I want to draw the distinctions very clearly.
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           In Janssen, the ANDA filer had stipulated to
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    infringement and validity of one of the patents.
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           So the Court said based on those actions, there is no
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    circumstances under which you can get a challenge to clear all
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    of the patents because you foreclosed one of them.
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           And then in the Impax case, Impax had agreed to be bound
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    by a judgment on one of the patents in another case. And the
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Court said because you agreed to this, there's no circumstances

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under which you can get relief as to all of the patents.

Cipla has not taken any actions which precluded from getting relief under the '509 and '510 patents.

And counsel, I think, will agree to that.

And so we're left with the question of does there actually have to be litigation at this moment on the '509 and '510 patent?

And there is a statement in the Dey case that acknowledges that in that case there was litigation pending on the other patent. And the statement is, as we have held under materially identical facts in Caraco, simply eliminating one barrier is sufficient so long as litigation is also pending that could eliminate the other barriers.

So in that case and in Caraco, there were parallel cases pending. But both of those cases involved parallel actions that happened at early stages. Somebody filed to clear the path. Because there was no dispute, they were going to have to have all of those patents in play.

And there's no dispute here that we need all the patents in play.

But if you read the collection of cases, Caraco, Janssen, Impax and Dey, part of the reason they allowed declaratory judgment in the Hatch-Waxman context is to prevent gaming of the system. They don't want the scenario where brands selectively don't assert patents so that they can use

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the regulatory scheme to prevent approval. That's why all of
those cases allowed declaratory judgment jurisdiction in this
context.
       And they talk about the gamesmanship that leads to the
decisions.
       So we have a situation here -- and I haven't found it in
any other case -- most likely Caraco, Janssen, and Impax are
all early stages of the litigation.
       Here we have the situation where the patent we're
fighting over is trial ready. The parties have everything in
the pretrial brief. We've spent two and a half years on this
patent. We're ready to go to trial Monday.
       If that patent doesn't get tried, it's going to be
another two years after we file a declaratory judgment on that
patent and the '509 and '510 patent.
       We are going to repeat everything we have just done, and
Teva is going to get rewarded for the gamesmanship of dropping
that patent at the pretrial conference.
       That's exactly what declaratory judgment in this context
is meant to prevent.
       Now, there's a question about the piecemeal
adjudication.
       I want to clear up -- the Hatch-Waxman scheme is
described in the Caraco case very well, and they say it's an
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artificial act of infringement for purposes of establishing

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jurisdiction in the federal courts, and the statute is 35 U.S.C. 271(e)(2).

The entire drug litigation for Hatch-Waxman is done under the specter of hypothetical situations.

Normally, in a patent case -- and they refer to them as ordinary patent cases -- somebody sells a product, and you are trying to stop them.

We all know what the conduct is.

Hatch-Waxman creates this artificial system where you file your application with the FDA, and in 45 days you start a litigation. In parallel with that, the FDA is reviewing your application, and so the entirety of the world may change in the context of your litigation.

The FDA may require you to tighten specs. The brand may change the label necessitating changes in the ANDA. There may be new guidance requirements that require changes to the ANDA. Everybody agrees the ANDA can change.

And what happens in the litigation may ultimately be rendered moot by the fact that you don't get approval or the approval requirements change.

So this is a context where the entirety of the litigation is speculative and could be rendered moot.

But, nevertheless, Congress has said we're going to strike this balance and give you this artificial jurisdiction so we can get generic drugs to the market faster.

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So it is a unique context. It is different, and I want
to be very clear. If this Court interprets the precedent as
requiring a case on the '509 and '510 patents, we haven't done
that yet. It is coming, but there was no reason to speed that
along. If it's not required, then we all agree we're going to
trial Monday on the '156 patent.
       And I want to talk about what happens if we get this
wrong just to be sure we're all on the same page.
       If the Court says there's jurisdiction, and we try it
and it turns out there wasn't, then nobody is worse for wear.
We're having the trial anyway. It's already tee'd up.
work is already done. Nobody is harmed.
       If there is jurisdiction and we don't try that patent,
there is no way to fix it for Cipla. We will be two years down
the road, find out we should have tried it, and there's no way
to make up for that time.
       And Teva benefits from the delay and Cipla is harmed.
       So if there is any question that it's close, it should
be that we try the patent to prevent harm because nothing harms
Teva by trying the patent.
       Unless you have further questions, your Honor.
         THE COURT: Counsel, the dismissal as to Cipla for
'509 and '510, that was in June of 2021?
         MR. ZIMMERMAN:
                        Yes.
         THE COURT: When that occurred, what was Cipla's
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    position?
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           Are you saying at that point they didn't know exactly
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    which patents were going to be required for ultimately to prove
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    the case?
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             MR. ZIMMERMAN: No, your Honor.
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           At that point in the case, we were still early on in
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    discovery, and Cipla said, okay, we will get these out.
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    will narrow the universe.
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           At that point, we expected that the first filer would
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    launch and trigger their own exclusivity. So we didn't think
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    we were going to have to clear the path.
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           We're now a year and a half later.
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           The first filer hasn't launched.
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           The FDA has reviewed Cipla's ANDA, and we're getting
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    closer and closer to approval. And so the parking issue has
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    become real.
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           And given that we hadn't expended a bunch of time and
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    effort on the '509 and '510 patents, we let them go at the
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    early stage. We are now realizing, okay, we knew we were going
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    to need the DJ on them as we got closer to trial and the first
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    filer hadn't launched. And so we're also going to need that on
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    the '156, but we've already expended all the effort on the '156
23
    patent.
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           That's why we're fighting so hard to keep it in.
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             THE COURT: Just one other point, and I don't need to
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    necessarily know the backstory to it, but when the stipulations
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    were entered as to Aurobindo, those had a provision for
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    noninfringement?
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             MR. ZIMMERMAN: For Aurobindo's stipulation?
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             THE COURT: Yes.
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             MR. ZIMMERMAN: I believe it did.
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             THE COURT: Okay.
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           Thank you, Counsel.
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                             Thank you, your Honor.
             MR. ZIMMERMAN:
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             THE COURT: Counsel.
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             MR. PICOZZI: Your Honor, I would like to begin where
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    Mr. Zimmerman left off, which was on the point about fairness
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    and gamesmanship.
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           Mr. Zimmerman just admitted that Cipla's predicament is
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    not the result of any gamesmanship on the part of Teva, but
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    calculations that Cipla itself made about what patents might or
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    might not be important when it agreed to dismiss those claims.
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           More fundamentally, though, each of the points that
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    Mr. Zimmerman raised during his presentation was an attempt to
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    add an additional exception to the rule against piecemeal
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    litigation that is not supported by a single case.
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           There is no exception, for example, on the basis of
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    fairness or efficiency and, in fact, the case law says the
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    opposite.
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           We cite several cases on the final page of our reply
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brief that explain why no such exception exists.

And those cases include the *Hercules* case, which is a Supreme Court case holding that because subject matter jurisdiction is jurisdictional, that fairness concerns and equity concerns don't matter.

The same is true of the First Circuit case that we cite as well as the District of Arizona case, which in a patent case very similar to this one, the Court dismissed for subject matter jurisdiction based on a covenant not to sue that was issued on the eve of trial.

The second punitive exception that Mr. Zimmerman referred to was that there was some distinction between early stage versus late stage litigation and that posture makes a difference.

In fact, no such exception exists, and none of the cases that anyone has cited refer to any such exception.

The final exception that Mr. Zimmerman refers to is -really goes back to the point of efficiency. That, well, we
should hear argument on the '156 patent because it is tee'd up,
and we may file DJ actions on the '509 and '510 patent.

Again, you know, there is not a single case in which the fact pattern supports that particular distinction. And, tellingly, Mr. Zimmerman does not say anything at all about the AbbVie case, which is a case by the federal circuit that interpreted Dey and applied the ruling in Dey that there must

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be pending litigation that would grant finality -- final
conclusion to the case or controversy.
       And in that case, again, the Court did not make any
exceptions based on any of the ones that Mr. Zimmerman has held
on.
       Unless your Honor has any further questions...
         THE COURT: Counsel, with regard to the requirement
that there must be pending litigation, are there any exceptions
to that?
         MR. PICOZZI: None -- certainly none that are in any
of the cases that either party have cited, and I'm not aware of
any.
         THE COURT:
                     Thank you, Counsel.
         MR. GREENBLUM: Your Honor, if I could just add one
thing to the question that you asked at the end of
Mr. Zimmerman's argument about the stipulation that Aurobindo
entered, just to crystalize it for the Court, because we
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The stipulation that Aurobindo agreed to and it was so ordered by the Court as to those patents and as to the '156 provided judgments but not findings based on evidence. And that was -- the parties here were unable to agree, that is Teva and Cipla. Cipla wanted those findings, and we didn't think they were appropriate or justified. And Judge Hammer said, well, look, I can't order a stipulation that the parties don't

discussed this and I handled it for Teva with Judge Hammer.

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agree to. And we understand that, but I just wanted to
crystalize for the Court. We remain amenable to a stipulation
that would enter a judgment on the '156 in the form that we had
submitted to Judge Hammer and submitted to Cipla without the
findings language.
       So I just wanted to be responsive to the Court's query
about stipulation.
         THE COURT: So that language then would read along the
lines of that the Court entered judgment of noninfringement as
to counts so-and-so?
         MR. GREENBLUM: Yes, your Honor.
         THE COURT: Okay.
      Mr. Zimmerman, anything further?
         MR. ZIMMERMAN: Your Honor, I just want to address two
points.
       The first one was there seemed to be a statement that
this is a problem of Cipla's own making. And I want to be very
clear on that.
       There was absolutely no dispute between the parties
until Teva dropped the '156 patent at the pretrial conference.
       Their actions are what necessitated this whole thing.
There was no problem at all. We were happy to try the
'156 patent.
       It is exclusively Teva's conduct.
       And the next point is the distinction they are drawing
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about you have to have pending litigation. That distinction --
so if I would have walked into the clerk's office this morning
and dropped off a '509 and '510 complaint, Teva's position is
that, okay, there is jurisdiction. Everything is fine.
try the patent on Monday.
       If I walk out of this hearing and drop it in the
courtroom -- in the clerk's office, they are saying there is no
jurisdiction because you didn't do it before the hearing.
       That can't be what the rule is with respect to
jurisdiction in this context.
       Thank you.
         THE COURT: One question for both parties.
       Regarding pending litigation, if the '156 was an aspect,
even taking '509 and '510 for example, so this case is not
finally concluded. So there's been no final determination in
this case.
       Pending litigation means that the claims themselves
still have to be active, I take it, is what the parties would
be saying as well.
         MR. PICOZZI: That's correct, your Honor.
         MR. ZIMMERMAN: That is correct, your Honor.
         THE COURT: Okay.
       While we're on the point of '156, just to review, I know
you have identified this specifically in the pretrial order
then, "the if and if not." So with regard to if it remains in
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1
    the case, what the impact is and if it's out of the case, what
    the impact is.
 3
             MR. GREENBLUM: Yes, your Honor.
             THE COURT: And that also talks about the claims
 4
 5
    meaning construction and things as well?
 6
             MR. GREENBLUM: I don't know if -- I think the
 7
    pretrial order would specify the claims that would need to be
 8
    construed.
 9
           I don't recall how much it discussed what the Court
10
    would need to do about it, but that would be in the Markman
11
    briefing before the Court.
12
             THE COURT: Understood.
13
           Just in terms of those claims, if '156 is out, what
14
    remains in the case as far as proof issues, but I'm sure that's
15
    spelled out in here.
16
             MR. GREENBLUM: That is certainly spelled out,
17
    your Honor. Yes.
18
             THE COURT: Okay.
19
           With regard to '156 in or out, do the parties have an
20
    idea -- and you probably spelled it out in here as well --
21
    what impact that would have on the trial schedule?
22
             MR. GREENBLUM: I know that at the conference we had
23
    in front of Judge Hammer in September, Cipla indicated they
24
    thought it would be very difficult to fit the trial into the
25
    four days that the Court has allotted if the '156 was in.
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           So I think we will get it done on the schedule that the
 2
    Court gives us.
 3
           We think it would certainly add a number of issues that,
 4
    for the reasons Mr. Picozzi explained, we think are
 5
    unnecessary. And it would certainly make it more difficult to
 6
    get it done in the allotted time.
 7
           I think we probably agree with Cipla about that.
 8
             THE COURT: Okay.
 9
             MR. ADAMS:
                         Your Honor, the '156 patent, I think, is
10
    pretty streamlined.
11
           If left in the case, the covenant not to sue on it, we
12
    have a very clear noninfringement position on it. I thing it
13
    doesn't change the fact that we can get this trial done in four
14
    days. I don't think it adds another day. I don't think that's
15
    the issue. So I think as we talked about the pretrial
16
    conference, it can still be done in four days.
17
             THE COURT: You won't get cut off if it ends up going
18
    past four days because we anticipated. We allotted more time
19
    than that as well. This is just more for the Court's own
20
    purposes in terms of anticipation.
21
           So you are not going to be foreclosed one way or another
22
    if your estimates or quesstimates are wrong with regard to it
23
    being in or out.
24
             MR. GREENBLUM: One thing I just want to comment,
25
    your Honor, in response to Mr. Adams is that it kind of goes
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1 back to the stipulation issue. 2 If all they needed was a judgment of noninfringement, I 3 agree with Mr. Adams. It wouldn't take up any time at trial. 4 They want findings. They want to put in evidence. They want 5 to put on expert testimony. Those are the things that are 6 necessary before the Court would make findings. That takes 7 more than -- you know, that's time. That's testimony. That's evidence that the Court would have to hear. 8 9 MR. ADAMS: Your Honor, we do want a finding, and let 10 me just clarify why. 11 The Hatch-Waxman statue doesn't just say a judgment. 12 says a finding of invalidity of noninfringement. So that's why 13 when we talk about why we can't agree to that language, Cipla 14 needs that to trigger the first filer, as Mr. Zimmerman 15 presented that. 16 But I think in terms of the procedure at trial, as 17 Mr. Zimmerman said, the '156 patent is ready to go. 18 In my opinion, the analysis of that '156 patent is 19 pretty streamlined. We have a covenant not to sue on it. Ιt 20 is a straightforward, noninfringement position. 21

Again, your Honor, I don't think it adds a lot of time to the trial. I think we still get the trial done in four days.

22

23

24

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MR. GREENBLUM: At the risk of having the Court reverse itself on you won't cut us off, the revised pretrial

order, as I read Cipla's position, reflects that if the Court exerts jurisdiction over the '156 and keeps it in the case, they are going to put on evidence asking the Court to make findings about invalidity on which a covenant not to sue would not be relevant.

So there would need to be claim construction from the Court, testimony from experts, documents, and argument about validity and that -- you know, so I don't think that the issue would be as simple as at trial here is the covenant, you're done, you can make findings.

You can't make findings based on a covenant, but you certainly can't make findings about invalidity.

THE COURT: With regard to that, a finding of noninfringement is not enough; Cipla is looking for more than that.

MR. ADAMS: Your Honor, a finding of noninfringement is enough for Hatch-Waxman to trigger.

The Hatch-Waxman statute says finding a noninfringement or invalidity. So this case is -- again, until right up to the pretrial conference, Cipla is ready to do both noninfringement and invalidity. That is why it is reflected in the pretrial order.

But, again, a finding of noninfringement, which I do believe is very straightforward in this case on the '156, is all Cipla needs from your Honor, and that's what we are looking

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    for.
 2
             THE COURT: The reason the Court asks, and unless I'm
 3
    missing something in the discussion, I understood that Teva was
 4
    offering a stipulation that provided similar language that they
    provided to Aurobindo, which did have noninfringement language
 6
    in it.
 7
             MR. GREENBLUM: It had language about a judgment of
 8
    noninfringement, not about findings based on evidence.
 9
             THE COURT: So we need a findings based on evidence,
10
    not a judgment of.
11
             MR. ADAMS: Your Honor, that's right.
12
           It's not because Cipla is trying to make this thing
13
    complicated or hard.
14
           It's we're tracking the statute.
15
           The Hatch-Waxman statute says a finding of
16
    noninfringement or invalidity. We are looking for that
17
    finding.
18
           Congress thought about this. In that statute, it says
19
    the parties could reach a consent order. The parties could
20
    agree to that language, submit it to the Court, and the Court
21
    could sign it.
22
           So Congress understood that. They said there could be a
23
    consent order where the parties sign that says a finding of
24
    judgment and noninfringement. We asked for that. Teva refused
25
    to give us that, but that's what we are looking for, finding of
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1
    noninfringement.
 2
             MR. GREENBLUM: Our position is that the stipulations
 3
    should just follow the courses, all of the prior ones, which
 4
    didn't make findings, because we don't think courts make
    findings based upon stipulations. Courts hear evidence in the
 6
    box and make findings.
 7
             THE COURT: Not to beat the point, but to beat the
    point, if the Court were to enter an order proposed by the
 9
    parties that has some sort of findings language, there would
10
    have been no formal findings by the Court.
11
           So I don't want to rehash the whole discussion that
12
    happened before Judge Hammer, but I'm realizing that maybe we
13
    might even had a discussion with counsel off the record between
14
    now and Monday. I may just look at the record just to get a
15
    little bit more understanding of what the language was that
16
    prevented the barrier to '156.
17
           At any rate, we will be prepared to render a decision on
18
    '156 on Monday.
19
           Was there anything else with regard to '156, or are we
20
    okay with '156?
21
             MR. GREENBLUM: No, your Honor.
22
             MR. ADAMS:
                         No, your Honor.
23
             THE COURT:
                         So we also have a Markman opinion that's
24
    prepared that the Court is also prepared to render on Monday,
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and I anticipate that there will, obviously, be some impact on

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your trial -- not preparation because I am sure you prepared on
everything -- but just in terms of how the trial proceeds once
you have the actual construction terms.
       With regard to those two decisions that we will be
rendering on Monday, we will have the opportunity to discuss in
more detail than in terms of what impacts, if there's any
additional concerns as far as counsel have in terms of proof
presentation, order of your case, or anything else.
       Now with regard to any particular issues, any particular
problems from a practical standpoint in terms of going forward
with trial, availability, any issues at all?
         MR. GREENBLUM: No, your Honor, we are prepared to
proceed on Monday.
       I quess one question I would have for the Court is:
Does the Court anticipate issuing the Markman and '156 rulings
in the morning?
       The question, the reason I ask is it will certainly
effect our opening presentation. I am sure it will effect my
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The question, the reason I ask is it will certainly effect our opening presentation. I am sure it will effect my colleagues' opening presentation, and we might need to just sort of work together with the Court on the timing of that to make sure we're not talking to you about things that are out or are in that we didn't anticipate being in.

THE COURT: We anticipate Monday morning or possibly...

And as a matter of fact, my dutiful law clerk just

reminded me, that because we've had these issues with the
motion and with Markman, is that you would do your actual
openings on Wednesday instead of Monday to give you an
opportunity to digest what we provide to you.
MR. GREENBLUM: One suggestion I would make without
talking to my team, which is always some peril, is to start on
Tuesday so that we could try to fit it in. Because witnesses
have come in and if we start it on Wednesday, I think under the
current schedule we wouldn't finish next week.
So if we got the rulings on Monday, we would be prepared
to be with your Honor Tuesday morning. I think that would suit
Teva.
THE COURT: We can accommodate Tuesday.
THE COURT: We can accommodate Tuesday. MR. GREENBLUM: Thank you, your Honor.
MR. GREENBLUM: Thank you, your Honor.
MR. GREENBLUM: Thank you, your Honor. One further minor housekeeping issue that that raises is
MR. GREENBLUM: Thank you, your Honor. One further minor housekeeping issue that that raises is that under the current pretrial order, the parties were to
MR. GREENBLUM: Thank you, your Honor. One further minor housekeeping issue that that raises is that under the current pretrial order, the parties were to exchange disclosures of their opening slides to one another to
MR. GREENBLUM: Thank you, your Honor. One further minor housekeeping issue that that raises is that under the current pretrial order, the parties were to exchange disclosures of their opening slides to one another to make sure there is no objections on Saturday evening before
MR. GREENBLUM: Thank you, your Honor. One further minor housekeeping issue that that raises is that under the current pretrial order, the parties were to exchange disclosures of their opening slides to one another to make sure there is no objections on Saturday evening before Monday morning trial.
MR. GREENBLUM: Thank you, your Honor. One further minor housekeeping issue that that raises is that under the current pretrial order, the parties were to exchange disclosures of their opening slides to one another to make sure there is no objections on Saturday evening before Monday morning trial. We would propose to exchange those Monday evening after

MR. ADAMS: Your Honor, I think part of the issue is

parties are fine with that as well.

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just the whole reason we agree upfront to exchange in time, it is generally 48 hours, is so that the parties can understand the evidence that they are going to present and they can understand our evidence and be prepared on that. I think Monday night is too late given where we're at.
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I think we all know both sides what potential constructions are going to be. Right? We've argued under theirs all through the case. They argued under ours all through the case. Our experts have opined on that. So I think we do know. I think now it would just be narrowing.

So I would suggest, if we're going to move the trial from Monday to Tuesday, we just move that date from Saturday to Sunday for the exchanges.

MR. GREENBLUM: Let me try to cut through this.

If we're going to get decisions from the Court on Monday morning, how about instead of Monday evening, Monday at 3 o'clock? I mean, the Court's constructions are going to materially affect my opening, to be honest.

THE COURT: Again, knowing what the universe of proofs are, if you did your exchange on Saturday and then you just did modifications after you received some rulings on Monday at least so there's not a complete surprise. I would assume that there would be things that would be coming out rather than new stuff going in.

MR. GREENBLUM: I think that that's true with respect

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    to the '156.
 2
           I think it's not true with respect to constructions
 3
    because the constructions the Court give us are going to be
    more than a guide to in or out.
 5
           They are going to be a guide to how we present evidence
 6
    to the Court.
 7
             MR. ADAMS: Your Honor, I would say his first
 8
    compromise, I think, would make sense, sometime earlier on
 9
    Monday instead of trying to, you know, do Monday night.
10
           I so think sometime earlier, maybe noon on Monday, would
11
    be a better time frame than trying to wait until Monday night.
12
             MR. GREENBLUM: We are down to three hours,
13
    your Honor.
14
           So let's see if we can close the deal.
15
             THE COURT: It sounds like it.
16
             MR. GREENBLUM: I am not in the habit of asking the
17
    Court what time it is going to issue its rulings.
18
           How about we agree on, you know, within four or five
19
    hours of receiving the Court's rulings on the docket?
20
             MR. ADAMS: That's great, your Honor.
21
             THE COURT:
                         Sold.
22
             MR. GREENBLUM: Thank you, your Honor.
23
             THE COURT: Anything else with regard to our
24
    housekeeping?
25
             MR. ADAMS: There is a couple of housekeeping items
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    from Cipla's standpoint.
 2
           The first one, I understand there was a stipulation
 3
    filed this morning. Cipla wasn't served with that stipulation.
 4
           As I understand it, it impacts Teva and Aurobindo.
 5
           So, I quess, the first point I would make is we haven't
 6
    seen it so we don't know what's in it. That is the first
 7
    point.
 8
           The second one, as I understand it, it is a stipulation
 9
    that Aurobindo will not be participating in the case, and
10
    that's ordered by your Honor.
11
           I understand Aurobindo had some witnesses.
12
           From our perspective, those witnesses shouldn't show up
13
    at trial. We -- Cipla doesn't control them. Their depositions
14
    shouldn't be used at trial.
15
           So we want to get some clarity to make sure that is what
16
    occurs with respect to the Aurobindo witnesses.
17
             THE COURT: With regard to that, Counsel.
18
             MR. GREENBLUM: Just to address that, your Honor, with
19
    respect to what it is, it's, as I think I described to
20
    Mr. Zimmerman before Court, it's a stipulation to stay and be
21
    bound. That's not uncommon in these types of cases.
22
           Essentially, Aurobindo is agreeing to live with whatever
23
    judgment the Court issues with respect to the dispute between
24
    Teva and Cipla. That happens all the time.
25
           I agree with Mr. Adams that they won't be participating
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in the trial. They won't be putting on their own argument, but that's what it is. It is fairly common, and I understood from the Court's clerk that the Court would be entering that. Unless the Court has questions, I can move on to the second point Mr. Adams made bout witnesses. THE COURT: You can move on to the second point, and then we will see what Mr. Adams has to say. MR. GREENBLUM: Sure. With respect to the second point, there were depositions of Aurobindo's witnesses. There is a schedule in the pretrial order for disclosure of designations of deposition testimony. We will meet that schedule, and we will disclose any deposition testimony that we intend to submit to the Court. We do expect that that will include testimony from Aurobindo witnesses. Cipla was given notice of those depositions and had an

opportunity to cross-examine if it wished. So I don't think there will be any surprise about what's in there.

The Court should recall that there's no dispute in this case that for infringement purposes the products of Aurobindo and Cipla are the same. So that's why witness testimony from Aurobindo would come in.

If there's to be a dispute about the admissibility of that, we're happy to meet and confer and to tee anything up for the Court that we need to, but they were given notice of the

1 depositions. 2 THE COURT: Okay. 3 MR. ADAMS: Your Honor, if I may respond on that 4 second point, the notice of the deposition is one thing. 5 There's testimony in there that has nothing to do with Cipla. 6 It's not related to any issue in the case that's relevant if 7 Aurobindo is out of the case. 8 So I think from our perspective there's -- we have our 9 Cipla will bring our witnesses. They are welcome 10 to cross-examine our witnesses. But playing deposition 11 testimony from a party who is no longer in the case just 12 doesn't make sense. 13 Certainly, it doesn't make sense in the context of 14 what's still relevant in the case and also in terms of the 15 timing and the way the case plays out. Having additional 16 deposition testimony from a party who is no longer in the case 17 doesn't make sense. 18 MR. GREENBLUM: If the objection is relevance, I am 19 very confident we are going to clear that threshold, but I'm 20 happy to meet and confer with Mr. Adams once we make those 21 designations in a timely fashion. And if we still have a 22 dispute about relevance, we will tee that up to the Court. 23 THE COURT: Perfect. 24 MR. GREENBLUM: One other housekeeping matter, 25 your Honor, is I recall that under the local rules of the Court

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there's an obligation of defendants in these types of cases to
regularly update their correspondence with the Food and Drug
Administration about their application. And I just wanted to
make sure that we continue to have a complete such file from
Cipla as we head into trial on Tuesday.
         MR. ADAMS: Your Honor, I'm happy to respond to that.
       We have.
       There is a local rule, seven days. We just literally
checked with the client. They told us no updates.
       I think this goes back to the point that Mr. Zimmerman
was making. This is a fluid process; right? It's not like
there is set product, and it's done.
       But we have. We checked with them, and we will continue
to do that and meet the local rule, seven-day requirement.
         THE COURT:
                    Thank you.
         MR. ADAMS:
                    And while I'm here, your Honor, I think
there's -- the issue of deposition, I think it is more of a
housekeeping question of what your preference would be, whether
you would prefer to have the deposition played live at trial,
whether you are looking for those depositions to be submitted
on the written record.
       The reason I raise it, number one, is timing-wise.
Number 2, obviously, our experts are going to be here.
are going to want to hear what the testimony is and be able to
provide their opinions and view that.
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           So we're just looking for your guidance in terms of your
 2
    preference for how the deposition designations are handled.
 3
             THE COURT: I am a little loathe to try and dictate to
 4
    counsel how they intend to present them.
 5
           I would ask that you confer to say is this going to be
 6
    presented via video or is this just going to be presented in
 7
    written form, so the Court will know as well that we will have
 8
    the necessary apparatus for you.
 9
           From my perspective, I don't have a preference one way
10
    or another in terms of the testimony coming in.
11
           The bigger concern is whether there's going to be any
12
    objection to what's coming in. Again, I'm going to rely on
13
    counsel to meet and confer on that and just let the Court know
14
    if there is going to be any issues with regard to that.
15
             MR. GREENBLUM: Understood, your Honor.
16
             MR. ADAMS:
                         Thank you, your Honor.
17
             THE COURT: Were there any other housekeeping items
18
    for defense, for Cipla?
19
           Those are your items?
20
             MR. ADAMS: That was our items, your Honor.
21
             MR. GREENBLUM: No, your Honor.
22
           Thank you.
23
             THE COURT: All right.
24
           Tuesday's start time will be 9 o'clock.
25
           We're here by 8:30, so the courtroom will be open by
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    8:30.
 2
           That will also give us an opportunity to confer if we
 3
    need to have any sort of conference before we start. That will
    also give us the opportunity, I don't want counsel to be overly
    pressed because I know you're going to be speaking on Monday as
 6
    well with regard to different forms of testimony and other
 7
    things.
 8
           So if we need to take an opportunity to conference first
 9
    before we go forward, you can let us know that on Monday.
10
    will be prepared to do that as well.
11
             MR. GREENBLUM: Thank you, your Honor.
12
             MR. ADAMS: Thank you, your Honor.
13
             THE COURT: Mr. Zimmerman.
14
             MR. ZIMMERMAN: Your Honor, just one logistical point
15
    that I think would help all of the parties from planning.
16
           I think everybody had planned to be here from Monday to
17
    Thursday. We're now starting on Tuesday.
18
           Does the Court plan to hold Court in this matter on
19
    Friday? So that we know what our schedule looks like. Because
20
    if you tell us four days, I think we can work together to do
21
    Tuesday, Wednesday, Thursday, Friday and have the trial done if
22
    the Court is available.
23
           I wanted to know what your schedule looked like in terms
24
    of whether Friday was an available trial day?
25
             THE COURT: I believe we are available Friday.
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           Yes, we are available Friday.
 2
             MR. ZIMMERMAN: Then I think counsel can get together,
 3
    and we can try this case in four days.
 4
             THE COURT: Again, we're not going to overly force you
 5
    to compress your case to do it. But if counsel feels they can
 6
    do that, and I think that based on what I'm seeing in the case
 7
    and seeing the level of preparation that was done, I would
 8
    think that we probably can get it done in four days.
 9
           In the event that we have to go further, we will.
10
             MR. ZIMMERMAN: And we appreciate the indulgence of
11
    not being rushed, your Honor. I've worked with counsel for
12
    years. We have done this many times. It's one of those that
13
    I'm very sure if we work together, we will present an orderly
14
    trial to get this done in the four-day period.
15
             THE COURT: Monday, we will have a 10 o'clock start
16
    time on Monday.
17
           You are starting on Tuesday.
18
           We will let you know when the opinions are available on
19
    Monday once they are filed electronically.
20
             MR. GREENBLUM: Thank you, your Honor.
21
             MR. ADAMS: Thank you, your Honor.
22
             MR. GREENBLUM: In other words, you don't need us here
23
    at 10:00 a.m. on Monday? We will just wait until we hear from
24
    the Court.
25
             THE COURT: No, I don't need you Monday.
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1
           Was there anything else?
 2
             MR. GREENBLUM: No. We appreciate the Court's time
 3
    today.
 4
             MR. ADAMS: Nothing else, your Honor.
 5
             THE COURT: I appreciate your time as well and the
 6
    preparation and your offers to have further discussion so that
 7
    we can make sure that we streamline things as much as we can.
 8
           Thank you both.
 9
           Thank you all, rather.
10
             THE COURTROOM DEPUTY: All rise.
11
    (Whereupon the proceedings are adjourned at 11:22 a.m.)
12
13
             FEDERAL OFFICIAL COURT REPORTER'S CERTIFICATE
14
15
             I certify that the foregoing is a correct transcript
16
    from the record of proceedings in the above-entitled matter.
17
18
    /S/ Melissa A. Mormile RDR, CCR, CRCR
                                                  11/10/2022
19
    Official Court Reporter
                                                  Date
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